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# **Analysing the co-evolution of embedded regulatory capabilities in firms and the state: the case of South Africa's medical device sector**

*Andrew Mkwashi, Dinar Kale, Julius Mugwagwa and David Wield*

## **1.0 Introduction**

Regulatory authorities in developing economies not only face challenges regarding their own capabilities, but also have to grapple with heterogeneous levels of technological and innovation capabilities in firms. This paper draws from a firm-level analysis of internally created knowledge, externally sourced knowledge and firm heterogeneity among medical device manufacturers in South Africa to consider the corresponding evolution, development and deployment of regulatory capabilities in firms in their efforts to comply with the country's health and allied products regulatory authority requirements. From this consideration, the paper explores possible broader adjustments in the country's medical device sectoral system of innovation which would promote, nurture and embed the desired regulatory capabilities in firms to enable medical device firms to be locally and globally competitive and to contribute optimally to the country's health sector objectives.

Medical device industries based in developing countries are few and generally focused on the low-tech part of the sector. The diversity and scale of health challenges in developing countries make the role of medical devices even more significant but according to WHO (2012) only 13% of manufacturers are located in developing countries. In developing countries, over 95% of the medical devices in public hospitals are imported, with very limited local production (Malkin, 2007). Moreover, most of the medical devices are inappropriate for local needs and unable to be sustained with the lack of local infrastructure (Lustick and Zaman, 2011). For example, WHO (2016) conducted a detailed analysis of medical devices policies from four selected countries in Africa (Ethiopia, Nigeria, South Africa and Tanzania) to identify opportunities for the development of local medical devices. The study found that there was a limited local manufacturing capacity and institutional mechanisms to incentivize manufacturers to engage in the production of priority medical devices. The same study revealed that there was lack of funds for research and development (R&D) and regulatory support to bring products into the market and to final users that could be of high public health value. Our paper focuses broadly on the persistent challenge of regulating the health sector, and particularly the medical devices subsector in developing economy settings where capabilities of the regulatory architecture are constrained by many factors relating to technological capabilities, market dynamics, actor interactions and firm heterogeneity, among others. We do this by analysing and interrogating the evolution and utilisation of embedded regulatory capabilities in medical device firms as an opportunity for strengthening medical device regulation in capability-constrained environments, using the specific case of the South African medical device sector.

## **2.0 South Africa's Medical Devices Sector – An Overview**

South Africa is the primary business hub for the medical device industry in Sub-Saharan Africa. According to Business Monitor International (BMI), the medical device market in South Africa is forecasted to grow from \$1.3 billion US to around \$1.7 billion US by 2021, riding on the

strong growth experienced from 2004 to 2013 (BMI, 2016). Local firms tend to be small or medium-sized businesses, with less than 50 employees and often combine distribution activities with manufacturing. The South African medical device industry is a highly competitive arena where small manufacturers are faced with multiple challenges that cause the companies to stagnate or fail (Deloitte, 2014).

Currently a significant proportion of firms that occupy the South African medical device industry are multinational corporations (MNCs) such as Johnson & Johnson, Medtronic, GE Healthcare, Siemens Healthcare and Philips Healthcare. Typically, these MNCs depend on their parent company to develop new products using R&D and regulatory resources housed in their headquarters. Few MNCs have in-country control of their product development activities, with spending on R&D in South Africa said to be minimal (SAMED, 2016). Most of the MNCs present in South Africa often operate in a joint venture capacity with local firms. Competing with MNCs is the most significant challenge for local SMEs or start-up manufacturers. As a result, they either become subordinate partners to the bigger MNCs, or simply sell out and leave the industry (Dawar and Frost, 1999). Those that persist, among others, leverage protectionist trade barriers or other forms of governmental support, such as local procurement quotas, to survive (Mkwashi, 2020, Maresova and Kuca, 2014) .

Demographic shifts such as ageing populations and technological developments underlie the long-term market opportunity for medical device manufacturers in South Africa. It is without doubt that the medical devices sector plays a critical role at each stage of the healthcare continuum, and has been instrumental in improving access and affordability of healthcare services. It is in this backdrop that an investigation into the regulatory constraints and realities that have led to a high dependence on imports for addressing domestic demand needs to be investigated. The regulatory constraints are not just for firms, but for the state too.

The main challenge that has been facing the South African government is to institute enforceable comprehensive medical devices industry rules, regulations and policies with the aim of promoting a national interest that includes the vibrancy of business enterprise (Mkwashi, 2020). Prior to 2017, only listed electronic products (also known as electromagnetic medical devices or radiation emitting devices) were regulated through the Hazardous Substances Act, No. 15 of 1973 and were required to be registered (CE certification) before they can be sold, leased, used, operated, or applied in South Africa (Saidi and Douglas, 2018). The rest of the medical devices were left unregulated, leaving manufacturers, wholesalers or distributors with few legislative formalities with which to comply (Mkwashi, 2020). Thus, the drive for improved regulatory systems and the establishment of a more effective regulatory framework in South Africa has been evident for the past two decades but despite political intentions and legislative revisions success has been limited to date (Keyter et al., 2018). In December 2016, the local regulatory framework governing medical devices underwent a substantial overhaul, when the Minister of Health published the regulations relating to medical devices and in vitro diagnostic medical devices (SAHPRA, 2020a). The production and use of medical devices was thereby subjected to a number of laws, regulations, strict standards, and certification processes.

## **2.1 The South African Health Products Regulatory Authority**

The South African Health Products Regulatory Authority (SAHPRA) is a semi-autonomous body established in 2017 by the National Department of Health. It assumed the roles of both the Medicines Control Council (MCC) and the Directorate of Radiation Control (DRC) (SAHPRA, 2020b). SAHPRA was tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. The aim of SAHPRA is to ensure access to safe, effective, good quality medical devices, create and maintain an ethical ethos of protecting and promoting human health, service excellence and integrity (SAHPRA, 2020b). The country's regulatory framework of medical devices is based on a four-tier, risk-based classification system for obtaining device licences for manufacturers, importers and distributors. A novel function assigned to SAHPRA was to ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVD devices. The continuous monitoring and evaluation of the safety, efficacy and performance profile of medical devices provide an opportunity for the management of risks throughout the medical device lifecycle. In addition, South Africa's medical device regulations are designed in line with the framework models used in developed countries because it was easier to follow the already learned, established practice. For example, upon renewal of the SAHPRA licence, manufacturers and distributors will have to provide evidence of ISO 13485 certification (SAHPRA, 2020a). Also, the requirements for importation and exportation of medical devices are similar to the internationally recognised certification programmes of the European CE Mark (Saidi and Douglas, 2018). This emerging regulatory environment is key for the performance and competitiveness of medical device manufacturers in South Africa, and the health sector broadly, hence the importance of analysing regulatory capabilities within the sector. An analysis of regulatory capabilities will also deepen understandings of the broader national and sectoral systems of innovation, which feed into and draw from the medical devices sector through interactions and co-creation of knowledge around products, processes and business or organizational models.

### **3.0 Analysing regulatory capabilities**

An analysis of embedded regulatory capabilities is a pertinent undertaking if regulatory compliance, a critical issue for all businesses, is to be achieved. Compliance is invariably an interplay and interaction among heterogeneous actors operating in specific institutional settings. In this paper we investigate the link between capabilities required for regulatory compliance, innovation systems and institutions in the specific case of medical devices. This paper seeks to enhance academic, policy and practice understandings of the evolution of embedded compliance capabilities through a context-specific unpacking of the processes underpinning innovation systems and institutions in the medical device sector. The contextual details arising from our qualitative analysis allow us to pay adequate attention to structural changes, which manifest in the continuous (re)organization of the processes within firms as they seek to attain and maintain compliance.

Our departure point is that regulatory compliance is and should not be an onerous or after-thought activity for firms in this sector, but an integral part of their processes for improving performance and enhance competitiveness. Viewed this way, regulatory compliance would seek to develop and leverage industry knowledge and regulatory capabilities to inform decision making within the firm and the wider ecosystem. There is a case here, as will be illustrated by the empirical data we draw from, of integrating regulatory compliance and the

requisite capabilities into a business-enhancing strategy for managing regulatory change and on-going compliance. The strategy will aim to maximise efficiencies and cost savings, mitigate risk of regulatory failure and will harness the best possible ways of ensuring that relevant officials in the firm are not only aware of existing and new regulatory requirements, but are also able to assess the effectiveness of current compliance frameworks and to benchmark the company's compliance arrangements against established and evolving industry best practice. Establishing and deploying policies and procedures for decision making which satisfies regulatory requirements and evolving expectations is a key part of the capability mix that is required.

### *The Innovation Systems Approach*

The innovation systems lens is important in this analysis in our view of the medical device sector as a sector driven by technology and technical change, key drivers of earlier Schumpeterian thinking on innovation and development (Cassiolato and Soares, 2015). Relatedly, Myrdal (1958)'s proposition that: contexts and institutions matter, positive and negative feedbacks have cumulative causation, and cycles may be virtuous or vicious is also crucial for our exploration of the dynamics and interactions in this sector. Also central to this thinking is Hirschman's (1958) point that interdependencies among different activities are important. Beyond that, the neo-Schumpeterian thinking that innovation is systemic, involving interaction among agents, rather than a linear process involving discrete steps, is also very important for this analysis as it reveals and locates the interplay between many agents, at firm and state levels, *inter alia*. We are keen particularly on the tacit nature of innovation – how it is embedded in people's minds or in routines and relationships, thus revealing how learning-by-doing matters as well as searching for outside technology (Lundvall, 2007). This is in addition to the knowledge from formal education systems and the wider science and technology (S&T) system, which a technology-intensive sector such as medical devices draws from.

Literature has accumulated since the 1970s about how firms acquire and develop technological capabilities particularly 'knowledge and skills required for production (where shop floor experience and 'learning-by-doing' play an important role) and for investment; as well as adaptive engineering and organizational arrangements required for the continuous updating of product design and performance features (Dahlman et al., 1987). This work showed not only successful stories of technological up-grading, but noted that a learning approach to technology ignored key elements, such as the role of institutions and in this paper, focus particularly on regulatory capabilities as part of innovation systems and the institutions that drive them. Besides filling a gap in literature on studies around regulatory capabilities in innovation systems, this paper also uses this case of the medical device sector to respond to a gap in the wider innovation systems scholarship, which is the dichotomy of how in developed countries, the focus is usually on the evolution and 'shaping' of innovation systems while in developing countries on 'construction' or 'creation' of innovation systems (Mytelka and Farinelli, 2003). Innovation is a context-specific and socially determined process, thus studying and learning from processes is important for both developed and developing countries. It is a social process in which most learning occurs locally, with the IS framework emphasizing the importance of the territory and local interactive processes. The issues discussed in most innovation systems studies underline the importance of understanding the

social process that facilitates innovation within a specific territory (the definition of which extends beyond geography and considers sectoral, social, economic and political factors). Relatedly, development scholars have noted that development is not merely the sum total of factors that drive development but is about the processes and interactions between “conditions” and “elements” that co-evolve to generate development (Wood, 1994:66). Lessons that can be gleaned from the medical device sector will thus be important for both innovation systems and development processes broadly. The systemic view inherent in the innovation systems framework allows a methodical analysis of the defining elements in the medical device sector. Innovation systems consider the entirety of all actors and environmental factors that contribute to innovation. The focus of the innovation systems approach can be on the level of national innovation systems (Nelson, 1993, Lundvall, 1992), regional or local innovation systems (Audretsch, 1995), technological innovation systems (Carlsson and Stankiewicz, 1991), or sectoral (Malerba, 2002). The perspective most applicable to medical device markets is the sectoral perspective.

### *Sectoral System of Innovation (SSI)*

Breschi and Malerba (1997) state that the sectoral systems of innovation (SSI) is: “that system (group) of firms active in developing and making a sector’s products and in generating and utilizing a sector’s technologies; such a system of firms is related in two different ways: through processes of interaction and cooperation in artifact-technology development and through processes of competition and selection in innovative and market activities”. The SSI is best suited to describe the dynamics of medical device sector in South Africa for a number of reasons. Firstly, the SSI framework in general focuses on supply as well as demand and on markets in the innovation process and is built on three pillars: actors and networks, knowledge and technologies, and institutions (Malerba and Mani, 2009). The framework selects some aspects from the systemic approach to innovation. These aspects are considered crucial elements in how the system works overall. Our study suggests that of these elements, only institutions have a predominantly national character. Secondly, the SSI places less emphasis on geographic boundaries and devotes greater attention to technologies, product classes and innovating firms. These aspects play a crucial role in shaping the South Africa’s medical device industry structure and evolution. Lastly, the SSI framework allows for the national, or even regional, components of the broader global sector to be envisioned as “sub-sectors”; nested within a broader global system of innovation (Malerba, 2005b).

In the SSI perspective it is realised that actors and networks are the heterogeneous agents composed of individuals or organizations and their interactions. The approach takes the sector’s firms which are active in developing and commercialising products, and in generating and applying a sector’s technologies, and looks at the processes of interaction with other organisations and institutions in the system through the lens of competition and selection in the market activities (Malerba, 2004). Firms are typically not only active in a local or national geographic area, but increasingly regionally and internationally.

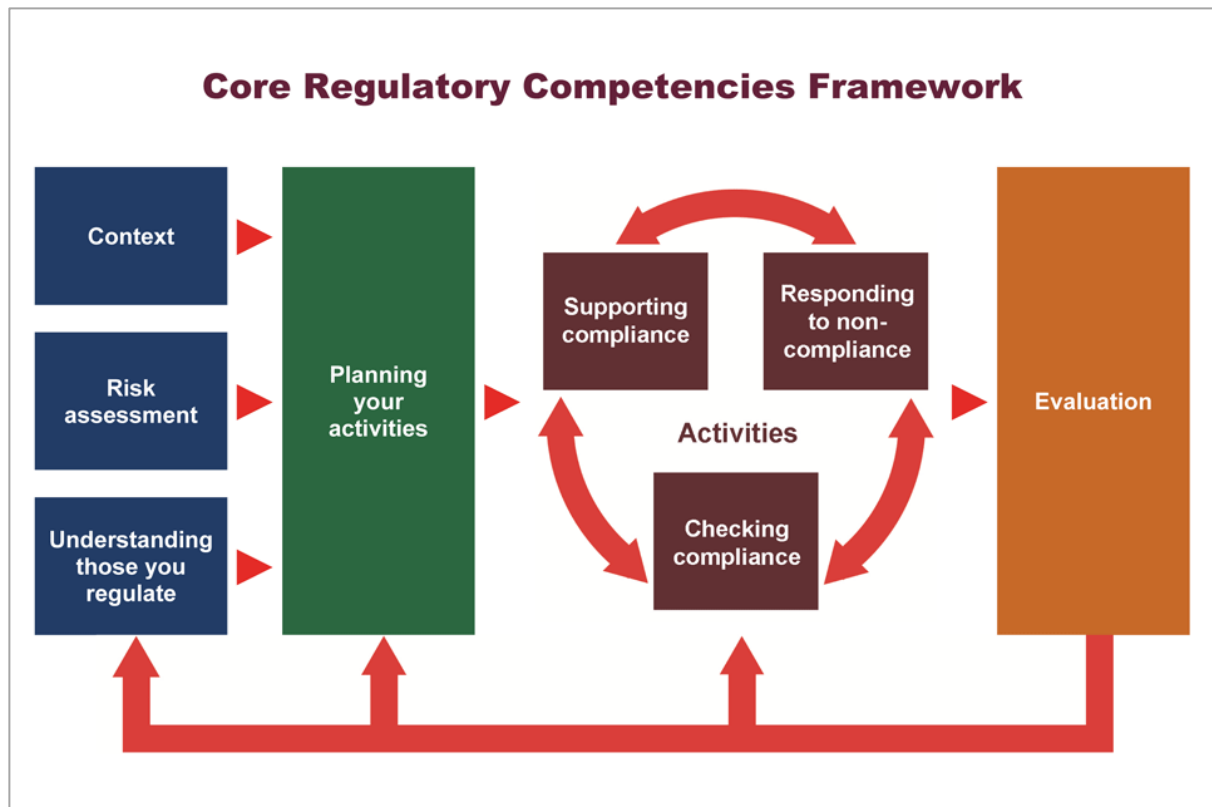
The SSI approach in the health sector has a knowledge base, technologies, input and demand where the actors are individuals and organizations at various levels of aggregation with specific learning processes, competencies, organizational structure, beliefs, objectives and behaviours (Malerba, 2004). Consistent with the evolutionary literature (Dosi, 1997, Nelson,

1995), knowledge is a key factor in determining technological change and it is essential for innovation. This knowledge is the source of sectoral boundaries and it is dynamic and change over time rather than to be fixed (Malerba and Mani, 2009).

The SSI approach considers the institutional framework and the actors in the system as key contributors to the system's dynamics (Cacomo, 1998). The institutions shape and regulate the actors' interactions. The flux in these elements results in a change and transformation in the system. Thus the SSI is a dynamic approach and it aligns well with the view that market outcomes in the medical device sector are determined by how the actors in the system interact under the influence of the institutional framework, particularly with regards to the elements of innovation under constraints put up by regulation and regulatory change. The fact is established that medical device firms operate in a regulation-intense environment which they need to understand and adapt to in order for them to thrive in their business (Mkwashi, 2020), and this paper adds to this perspective by taking a close look at the firm-regulation interface in South Africa from the point of view of firms as key actors in the regulatory system. We will argue that a clearer understanding and ability by the firms to navigate knowledge systems at play in the sector, especially in an environment of economic and market heterogeneity and uncertainty such as South Africa, will enable the regulatory infrastructure to be able to help create and sustain a mutually-beneficial firm-regulation interface.

### **3.1 Regulatory capabilities – what are they?**

As innovation occurs, it is important that regulatory professionals stay relevant and have the necessary skills and competencies to make substantive contributions to their organisations (Drago et al., 2017). The UK government developed a guidance framework that can be used to analyse and assess core regulatory competences (see Figure 1). Core or generic competencies in the medical device sector would be those that are specific to the regulation of medical products, spanning all the regulatory functions. This is important to support the development of an agile workforce and facilitate movement not only between regulatory functions, but also between sectors, e.g., from industry to government and vice versa (World Health Organization, 2019).



**Figure 1.** Core regulatory competencies framework.

Source: <https://www.gov.uk/guidance/core-competencies-for-regulators>

We adapt and deploy the framework above to represent not only a tool for national regulatory authorities (NRA) development, but also a continuum of the NRA's capabilities in performing regulatory functions on behalf of the state. Thus, the competency framework for regulators allows competency modelling by individual NRAs and aligns individual capabilities with the organizational strategy and business processes (World Health Organization, 2019). Our argument in this paper is that such a framework concomitantly gives clarity and direction for firms to develop and situate the capabilities they require to be compliant with regulatory requirements.

#### 4.0 Methodology

In order to provide some valid and reliable scientific claims from the research process, a mixed-method approach was used (Bryman, 2007). Mixed methods, in which quantitative and qualitative methods are combined, are increasingly recognized as valuable, because they can capitalize on the respective strengths of each approach (Jick, 1979, Tashakkori and Teddlie, 2010). The main method of collecting primary data for this study was semi-structured in-depth interviews with South African medical device sector key stakeholders. The categories of respondents included medical device manufacturers, government officials, regulatory agencies, academic and research institutions and industry associations. These interviews allowed the researchers to gain a deeper understanding of the competitive forces experienced by firms in the medical device industry, the limitations within the industry, the obstacles faced by firms in developing and deploying regulatory capabilities and key success factors in the firm's survival and growth. A total of 48 interviews were conducted during a



field study between October 2016 and May 2017 and these interviews, augmented by regular updates and follow-up after the field study period, provide the basis for the analysis and narrative underpinning this paper. In addition to this being the first extensive study of this nature covering out focus country, this study also chose South Africa for the following objective reasons: firstly, it is one of the African Biomedical Engineering Consortium (ABEC) countries that has implemented or harmonized with European directives in its legislation, despite the fact that the legislation is particularly strict (De Maria et al., 2018). Secondly, the legislative framework of South Africa adopted the International Medical Device Regulators Forum (IMDRF) philosophy of accelerating international medical device regulatory harmonization and convergence (IMDRF, 2020). Thirdly, South Africa adopted the Risk Classification System formulated by the Global Harmonization Task Force (GHTF) that has drawn the interest of policymakers and regulators in many countries.

Ethical considerations were vital in the conduct of this research as it involved collection of data from people and organizations. Ethics approval was thus obtained from the Open University's Ethics Committee for all phases of the research. Necessary steps for ensuring anonymity and confidentiality were designed into the research schedule. Prior to the interviews, informed consent to participate in the interview was obtained from each interviewee as outlined in the ethical procedure spelt out from the Open University Ethics Committee.

Thematic analysis (Boyatzis, 1998) was used for analysis and interpretation of the largely qualitative data that was collected for this study. NVivo software was used to aid data management, and its organisation into codes, categories and themes. Our analysis of findings below situates the views of respondents on regulatory capabilities in the context of interactions between firms and the state, within the framework shaped by the emerging regulatory environment for medical devices.

## **5.0 Findings and Analysis**

### ***Regulation as a defining institutional element of the sectoral systems of innovation***

In the sectoral systems of innovation institutions include norms, routines, common habits, established practices, rules, laws, standards, etc. These institutions affect the actions, cognition and interactions of sector participants (Malerba, 2005a)<sup>1</sup>. Similarly, Furubotn and Richter (2005) echoed that the way in which actors in the sectoral system participate and contribute to innovation is affected by the environment in which innovation takes place. It is important to realise that institutions do matter, and time does as well. While regulation typically encompasses codified law and non-codified structures in medical devices, the codified rules determine the entry of new products and technologies to the market<sup>2</sup>. Different studies have drawn attention to the effects of regulations; on one hand research has highlighted that regulations have forced firms to focus more on innovation capability to comply with regulations and on the other hand this has become a barrier for firms leading to

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<sup>1</sup> Regulation in this context is only one element of the institutional framework within which the innovation system operates.

<sup>2</sup> Regulation encompasses not only the codified rules, but also the standards that actors in the market are expected to adhere to.

their exit. Our findings highlighted that regulations play a major role in affecting the rate of technological change, the organization of innovation activity and performance. Our findings further confirm that whilst the state, through competent authorities, seeks to ensure that the requirements of the regulations are applied, the extent to which this is feasible is dependent on the manufacturing firm's capabilities to respond and deploy the new regulatory environment. Teece et al. (1994, p.18) define these capabilities as "a measure of the firm's ability to solve both technical and organizational problems". The firm-level technological capabilities therefore determine what the firm is potentially able to do in response to the new regulatory demands. In tables 1 and 2 below, we draw from our data to present a comparison of required and available capabilities in MNCs and local firms.

- What respondents say about the regulatory capabilities required and available

Table 1: Levels of importance and availability of capabilities in MNCs

<b>MNCs</b>		
<b>Regulatory capabilities</b>	<b>Level of importance of capability</b>	<b>Level of availability of capability in firm</b>
R&D investment	Medium	Medium
Recruitment and training	High	High
Innovation in production	Medium	Medium
Compliance capability	High	High
Risk management capability	High	High
Quality Control capability	High	High
Linkages between firms	High	High
Linkages between firms and regulators	High	Medium

Table 2: Levels of importance and availability of capabilities in SMEs

<b>SMEs</b>		
<b>Regulatory capabilities</b>	<b>Level of importance of capability</b>	<b>Level of availability of capability in firm</b>
R&D investment	High	Low
Recruitment and training	High	Low
Innovation in production	Low	Low
Compliance capability	High	Low
Risk management capability	High	High
Quality Control capability	High	High
Linkages between firms	High	High
Linkages between firms and regulators	Low	Low-Med

From the above tables, we can deduce that while the different capabilities are important for both large and small firms, their availability is limited in the small firms, limiting the overall regulatory capability in these firms, which in turn limits their ability to comply with the regulatory requirements. As highlighted by other scholars, for example (Nkambule, 2018), the factors that lead to low regulatory capabilities in small firms in particular and developing countries broadly, relate to the lack of appropriately qualified, trained and experienced

regulators in the competent authority and in the firms. For example, some respondents highlighted that, SAHPRA inherited employees from the MCC, whose expertise is in the regulation of medicines, therefore, a shortage of skilled personnel to attend specifically to medical devices was likely, unless staff recruitment was to be undertaken and in-house training was to be put in place. Recognising this, SAHPRA has been encouraging a “capacity building” component in a clinical trial application process, a thrust that speaks directly to the national imperative for enhancing regulatory capabilities in South Africa (Nkambule, 2018). Further, as a competent authority, SAHPRA does seem to acknowledge that to successfully implement medical device regulations, stakeholders in the medical device industry collaborate. Our data points to the need for manufacturers to have embedded capabilities (i.e. the necessary expertise and experience) in order for them to know how to execute the regulations. Thus, the proactive engagement of different stakeholders from the medical device industry as partners in the implementation of the regulations would be beneficial to the sector.

### ***Actors and Networks as sources of regulatory capabilities in South Africa’s medical device sector***

The term “actors” used in the innovation literature refers to both groups of individuals and organisations operating within the system or sector of interest. These actors could include consumers, entrepreneurs, scientists, firms, universities, financial institutions, government departments, etc. Sub-groups, such as departments within firms, can also be regarded as actors (Malerba, 2005a). South Africa-based medical device firms are key actors in innovation and production in the sectoral system. These firms are characterized by specific learning processes, capabilities, competencies and organizational structures, as well as by beliefs and, expectations and goals (Nelson and Winter, 1982, Teece and Pisano, 1994, Dosi et al., 2000). Within South Africa’s medical device sector, firms are connected in various ways through market and non-market relations. Thus, relationships between firms and non-firm organizations (such as universities and public research centres) have been a source of innovation, regulatory capabilities and change in the sectoral system.

- What respondents say about sources of regulatory capabilities

In Table 3 below, we summarise our findings on the diverse sources for the capabilities that are required by both the state and firms to ensure compliance with regulations.

Table 3: Sources of regulatory capabilities in South Africa’s medical device sector

<b>Sources of capabilities in SA</b>		
<b>Regulatory capabilities</b>	<b>MNCs</b>	<b>SMEs</b>
<b>R&amp;D</b> ( <i>Investment, Design concept, Develop concept and Prototype development</i> )	<ul style="list-style-type: none"> <li>- Academic institutions</li> <li>- SMEs</li> <li>- Government</li> </ul>	<ul style="list-style-type: none"> <li>- Venture capitalists</li> <li>- Incubators</li> <li>- Government</li> <li>- Academia</li> <li>-MNCs</li> <li>- Industrial Development Corporation</li> <li>- Banks</li> <li>- Other investors</li> </ul>

<b>Recruitment and training</b>	<ul style="list-style-type: none"> <li>-South African National Accreditation System (SANAS)</li> <li>-In-house trainings</li> </ul>	<ul style="list-style-type: none"> <li>- Role of MNCs</li> <li>- SANAS</li> <li>- Established academic institutions</li> </ul>
<b>Innovation in production</b> ( <i>Device design, Clinical trials and field testing and manufacturing</i> )	<ul style="list-style-type: none"> <li>- Role of SMEs</li> <li>- MCC/SAHPRA</li> <li>- South African Bureau of Standards (SABS)</li> <li>- Biosafety Legislation (BSL)</li> <li>- Accreditation/ Notifying bodies</li> </ul>	<ul style="list-style-type: none"> <li>- Government</li> <li>- Regulatory agencies</li> <li>- Strategic Health Innovation Partnerships (SHIP)</li> <li>- Global Health Innovation Accelerator (GHIA)</li> <li>- Industrial Development Corporation</li> <li>-Banks</li> <li>- Venture Capital investors</li> </ul>
Compliance capability	<ul style="list-style-type: none"> <li>- MCC/SAHPRA/SABS</li> <li>- BSL</li> <li>-Accreditation/ Notifying bodies</li> </ul>	<ul style="list-style-type: none"> <li>- Government</li> <li>- Regulatory agencies</li> <li>- SABS</li> <li>- BSL</li> </ul>
Risk management capability	<ul style="list-style-type: none"> <li>- Policy formulators and implementers.</li> <li>- Risk management standard ISO 14971.</li> <li>- Essential Principles of Safety and Performance documents.</li> <li>- Code of Practice for industrial radiography</li> </ul>	<ul style="list-style-type: none"> <li>- Policy formulators and implementers</li> <li>- Risk management standard ISO 14971</li> <li>- Essential Principles of Safety and Performance documents</li> <li>- Code of Practice for industrial radiography</li> </ul>
Quality Control capability	<ul style="list-style-type: none"> <li>- Quality management standards e.g. ISO 13485 and ISO 9001</li> </ul>	<ul style="list-style-type: none"> <li>Quality management standards e.g. ISO 13485 and ISO 9001</li> </ul>
Linkages between firms	<ul style="list-style-type: none"> <li>- Resources from external partners (SMEs, start-ups, authorized representatives, importers &amp; distributors)</li> </ul>	<ul style="list-style-type: none"> <li>- Resources from external partners such as MNCs, start-ups, critical subcontractors &amp; crucial suppliers.</li> </ul>
Linkages between firms and regulators	<ul style="list-style-type: none"> <li>-Industry associations</li> <li>- Government</li> <li>- Regulators</li> </ul>	<ul style="list-style-type: none"> <li>-Industry associations</li> <li>- Government</li> <li>- Regulators</li> </ul>

From the table, we can argue that the sources and support for medical device firms' as well as state regulatory capabilities can be viewed in the context of the medical device life cycle. Launching a medical device in South Africa was highlighted to be a challenging process, involving several steps that ensure the product meets all regulatory requirements. Medical device incubators and accelerators help start-ups while small businesses develop and take products to the market. Networking opportunities and capabilities are this valuable for these actors, to enable them to access funding, innovation support and other resources to build infrastructure and get ideas transformed into reality. Both the state and firms, with support from intermediary bodies, have got a role to play in creating the spaces and opportunities for collaboration, co-creation of and co-evolution towards the required capabilities.

The practice of regulating medical devices effectively and efficiently requires appropriate individual expertise, reinforced by the institutional capacity of the regulatory authority, to act according to good regulatory practices (WHO, 2017). Governments have a key role to play in promoting, directing and accelerating the learning process (Nübler, 2014). Policies to

promote the development of productive and embedded regulatory capabilities relate to different areas and require a comprehensive and coordinated strategy. South Africa has established institutions that can be used as sources for biomedical/clinical engineering education and research as well as training programs for medical device technicians. For example, biomedical/clinical engineering training exists at the leading South Africa's universities such as Tshwane University of Technology, University of Cape Town, University of Stellenbosch, and Witwatersrand University (WHO, 2015). The Clinical Engineering Association of South Africa also provides training to medical device technicians (CEASA, 2018). The role of the government is also significant in ensuring support for local production, but equally critical is the role of academia to train biomedical engineers, clinical engineers, regulatory science professionals and other professionals capable of translating local needs into action and finding appropriate local solutions based on international best practices. It is generally agreed that while beneficial in some respects, South Africa's institutional context has historically not provided an environment conducive to research and development for novel medical devices and also contributed to the underdevelopment of the country's medical device regulatory capabilities (De Maria et al., 2018).

MNCs are involved in discovery and commercialization processes. The special role of large companies is to contribute infrastructure, market knowledge, and financial resources to validate technologies and make them valuable to patients (Pope et al., 2001). These MNCs have the ability to bring scale to the challenge of globalization and successful product development. Furthermore, MNCs can supply capital and credibility. With the exception of large medical device firms, few SMEs have the ensemble of regulatory capabilities. Indeed, even large firms are increasingly outsourcing much of the innovative activities to specialized firms. Therefore, related innovations provide an opportunity for the often-distinct expertise and actors to pool their knowledge, and other resources, to develop a given product. In fact, MNCs are already playing a key role in SA in the growth of the medical device industry through acquisitions, joint ventures, strategic alliances, contract research, licensing and royalty agreements (Mkwashi, 2020).

International quality standards are also good sources of regulatory capabilities. They have been applied to the design, manufacturing and distribution of medical devices. Such standards are aimed at ensuring that customers receive products that meet both regulations and safety expectations (Cheng, 2003). For example, compliance with the ISO 13485 quality management system, which prioritises risk reduction and safety, is a requirement for producing medical devices with a risk classification above Class I (Mitra, 2016). The local manufacturers of radiation emitting devices in SA have also learned to adopt the "Code of Practice for industrial radiography - X-ray Equipment" as an embedded regulatory mechanism to manage potential risks.

The role of medical device industry associations is to advocate for innovation and to help its member companies move through the regulatory and public policy processes. Because regulation is the result legislation to affect change either in the regulatory process or within public policy, industry associations and researchers need to be players in the broader policy and political debates (Pope et al., 2001). Due to the changing pattern of government and industry relationships, information sharing and collaboration become essential or

unavoidable and this impacts on the manner in which the innovation process is organized (Malerba and Adams, 2014, Mkwashi, 2020).

Critical subcontractors and crucial suppliers are also other import sources and support for medical device firms' regulatory capabilities. The critical subcontractors ensures all or part of the medical device's design, or performs all or part of the manufacturing processes, or carries out all or part of an activity in relation to regulatory requirements (e.g. post-market data collection). Crucial suppliers on the other hand provide finished devices, or key sub-assemblies essential to the performance of the medical device, or critical raw materials.

- Constraints for obtaining and sustaining the capabilities

In this study, we examine regulatory constraints for obtaining and sustaining capabilities by analysing regulatory design. In Table 4 below, constraints for both the state and firms are summarized and organized according to the three categories (Lack of knowledge, willingness to comply, and ability to comply).

Table 4: Constraints for obtaining and sustaining the capabilities in South Africa's medical device sector.

<b>Stakeholder Category</b>	<b>Lack of Knowledge</b>	<b>Willingness of stakeholders to comply with regulations</b>	<b>Ability of stakeholders to comply with regulations</b>
<b>SMEs</b>	-Requirements are too complex to know and understand.	-Voluntary compliance is low when costs (in time, money, or effort) are considered to be high. - Most firms seem to view regulatory agencies as a police officer rather than a partner.	-Costs of Compliance. SMEs disproportionately high for SMEs based on their size and turnover, and affect SME compliance rates. - Failures of administrative capacity -Bureaucratic protocols
<b>MNCs</b>	-Uncertainty as a barrier to innovation.	-Overly legalistic regulation in the form of failure to consider arguments by regulated enterprises. - Failures of prior consultations with firms	-Lack of calibration authorities. - Significant delay in research ethics approval
<b>Regulators</b>	Regulator dependence on over-committed external expertise		-Limited local capacity for auditing facilities. - Failure to monitor regulatory compliance as regulators have relied on self-regulation or co-regulation with the aim of increasing voluntary compliance. - Failures of administrative capacity

SMEs play an important role in the product development ecosystem, but SMEs in South Africa are often struggling with the regulatory complexities of the medical devices development cycle. Most of the industry stakeholders confirmed that regulatory requirements are too complex to understand and compliance costs are generally higher for SMEs, suggesting that there is a higher risk of compliance failure. If the costs of compliance appear disproportionately high compared with the potential of a market, or if regulatory requirements are not harmonized with those of other countries, manufacturers and importers may be discouraged from offering their products and that may impede achievement of national public health goals (WHO, 2017).

A majority of SMEs argued that the bureaucratic protocols caused by the regulatory environment slowed the process of innovation and their ability to comply. These firms stated that there are lots of documentations and administrative procedures to bring a product in to the market that inevitably impede innovative outputs. Most firms seem to view regulatory agencies as a police officer rather than a partner, thus affecting their willingness to comply with regulation.

One of the biggest regulatory constraints in SA is lack of calibration authorities. Calibration according to SANAS means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and corresponding values realised by standards whatever their uncertainty. The respondents highlighted that if they have equipment that might need to be calibrated, the firms will have to send the equipment overseas and this process is very expensive.

Some MNCs highlighted that there is an overly legalistic regulation in the form of failure to consider arguments by regulated enterprises. These MNCs echoed that, SA is an attractive location for conducting clinical investigations in Africa. However, delays in the ethics approval process, estimated at six months on average, are thought to be a significant stumbling block preventing the industry from reaching its potential in clinical research. The involvement of multiple bodies, such as Southern African Radiation Protection Association (SARPA), the Medical Research Council (MRC) Ethics committee and Radiation Control Directorate (RCD) are contributing factors to these delays, with the last two perceived as primarily responsible.

Historically SA's Medicines Control Council (MCC), which was superseded by SAHPRA, faced resource constraints as workloads placed on the regulator steadily increased. As a result the MCC became dependent on over-committed external expertise. Evaluation structures which relied on external evaluators lacked effective performance management contracts and did not provide a sustainable mechanism for timely submission of evaluation reports (Keyter et al., 2018).

In Table 5 below, we draw from our empirical findings to illustrate some examples of where embedded capabilities have proved helpful in the South African medical device sector.

Table 5: Examples of where embedded capabilities have proved helpful

<b>Recruitment and training capability</b>	<b>Regulatory Compliance</b>	<b>Risk-Based Approach</b>	<b>Quality Control capability</b>	<b>Linkages</b>
<ul style="list-style-type: none"> <li>-Use of advisory groups</li> <li>- Early interactions and consultations on new regulatory change</li> </ul>	<ul style="list-style-type: none"> <li>- The establishment of Regulatory Compliance unit of SAHPRA responsible for the enforcing and monitoring regulatory compliance</li> </ul>	<ul style="list-style-type: none"> <li>-Risk-based approach maximizing the impact of regulatory investments</li> </ul>	<ul style="list-style-type: none"> <li>- Firms that embraced quality had fewer negative events to address</li> <li>- QC tests played an important role in diagnostic imaging to limit the population dose growth, thereby improved quality control</li> </ul>	<ul style="list-style-type: none"> <li>- International company-to-company partnerships</li> <li>- Target-based collaboration harmonized the industry actors and facilitated growth of the industry</li> </ul>

There are a number of ways in which embedded regulatory capabilities and regulatory processes for medical devices in SA have proved helpful and improving. These include the use of advisory groups within regulators that can bring data, insight and knowledge to the medical device development ecosystem, expedited reviews for breakthrough and highly beneficial innovations, early interactions and consultations on new regulatory changes, reducing inspection burdens on companies with an excellent compliance track record, increased access particularly for SMEs and better coordination within MCC/SAHPRA with respect to combination products.

The establishment of Regulatory Compliance unit of SAHPRA has proved helpful in monitoring and control of border posts for imports and exports of health products, preventing and monitoring of unregistered health products, counterfeits, substandard and falsified medical devices (SAHPRA, 2020b). This embedded regulatory capability has also helped in the monitoring and eradicating emerging illegal retail outlet selling of healthcare products and stopping the illicit manufacturing facilities and ensuring that unregistered healthcare products are removed from the public. SAPHRA is now using a risk-based approach that seeks to channel available resources to regulatory functions and activities that are most likely to facilitate access to quality-assured products and identify and address high-risk quality problems, thereby maximizing the impact of regulatory investments.

SANAS entered the market as control actors and certifiers of manufacturers' quality management system (QMS), a central role in SA's radiation emitting device regulations. The embedded capabilities in the SANAS annual quality control (QC) tests include preventive maintenance procedures, administrative methods and training. They also include continuous assessment of the efficacy of the imaging service and the means to initiate corrective action (Fiedler, 2017). Most of stakeholders in SA were in agreement that the introduction of the QC tests has played an important role in diagnostic imaging to limit the population dose growth, thereby improved quality control. The inspection of facilities involved in product development and along the supply chain is integral to assure the quality of medical products. Inspections conducted in accordance with international standards, norms, and guidelines reveal weaknesses and deficiencies as well as actual or predictable errors in production, quality control, storage, or distribution (WHO, 2018).



In the past the MCC did not have a dedicated Quality Management Unit, however, contingencies have been put in place to establish such a unit. This unit is responsible for formalizing the implementation of the QMS for the authority and for performing internal quality audits and for implementing strategies geared for continuous improvement. Through the application of a robust QMS underpinned by the drive to cultivate an integral quality culture the regulatory performance and responsiveness of SAHPRA has been enhanced.

## **Discussion**

In this section, we discuss our findings on various key aspects around key themes on embedded regulatory capabilities as set out in our conceptual and methodological process and empirical findings above. As highlighted, this study makes an argument that a strong understanding among actors and ability to navigate knowledge systems at play in the sector, especially in an environment of heterogeneity and uncertainty such as South Africa, will enable the regulatory infrastructure to be able to help create and sustain a mutually-beneficial firm-regulation interface.

### *Knowledge requirements for regulatory policy execution*

The knowledge base of a sector plays a central role in innovation and greatly affects the types of learning and capabilities of firms (Malerba and Mani, 2009). With respect to the nature of the underlying knowledge within the SSI framework, factors such as specificity, tacitness, complexity, independence, and the means of knowledge transmission are viewed to play an important role in a regulatory regime (Malerba, 2005b). For many years, South Africa government has faced dynamic complex issues that prevented the achievement of optimal regulatory implementation. Some of these issues are due to the knowledge requirements needed to execute regulatory policies effectively. However, knowledge is highly idiosyncratic at the organizational or firm level, does not diffuse automatically and freely among actors, and has to be absorbed by organizations or firms through their differential abilities accumulated over time (Malerba and Mani, 2009). Therefore, having an awareness of the context under which regulatory capability develops would be a big advantage and let the organization gradually build its knowledge-based system (Alrabiah and Drew, 2020). The development and application of regulations calls for a well-trained, scientifically engaged and motivated workforce. Hawkins (2000) argued that insufficient knowledge and inadequate information of regulators can be threats to regulatory processes. Regulators are supposed to not only have a deep understanding of the role regulation play as a tool of government but also have the understanding of the role and responsibilities of partner organisations. Regulators must be able to work within the wider regulatory framework, work towards regulatory objectives, and within regulatory policies and procedures. Our case study results revealed that the efficacy of regulators depend on their knowledge, and that this is positively related to the knowledge possessed by the regulated firms. Our case study further illustrates how enabling regulation serves both as the legislative mandate for the competent authorities to act, and as a starting point for these regulators' discretion and oversight. The enabling content will allow for the control and the evaluation of the performance of the regulation. The latter can only be carried out where a well-defined and focused set of objectives in the founding regulation exists (Frank, 2003).

### *Risk assessment*

Effective local regulation depends upon the regulators' ability to assess regulatory risks and the understanding of risk management in a business context. Risk Assessment evaluates the likelihood and potential severity of significant risky outcomes, and it uses that analysis to place the situation into crude categories of " high, " " medium, " and " low " risk (Weinberg, 2011). By basing their regulatory work on an assessment of the risks to regulatory outcomes, regulators are able to target their resources where they will be most effective and where risk is highest (BERR, 2007). As such, in order to carry out comprehensive and effective risk assessment, regulators must ensure that risk assessment precedes and informs all aspects of their approaches to regulatory activity such as inspection programmes, advice and support programmes, and enforcement and sanctions. Herbst and Fick (2012), whose study focused on SA regulation, radiation protection and the safe use of X-ray equipment indicated that poor risk management of regulatory system, lack of financial resources and deficient human regulatory capacity put the health and safety of the local population at risk. As such, risk assessment should include explicit consideration of the combined effect of the potential impact of non-compliance on regulatory outcomes; and the likelihood of non-compliance (BERR, 2007).

### *Understanding those you regulate*

Regulators within the scope of core regulatory competencies framework are diverse but they share a common primary purpose – to regulate for the protection of the vulnerable, the environment, social or other objective. Regulators should have an understanding of the current business environment and the business sector(s) regulated. South Africa's current business environment has developed a distribution infrastructure based primarily on-imported medical devices and for a long time had limited regulation requirements. Furthermore, five out of seven new small businesses in South Africa fail within their first year (Leboea, 2017). Therefore, to have an effective regulatory framework, SA regulators must have an ability to engage constructively with business and an ability to tailor their approach to businesses and individuals that they interact with taking into consideration the fact that it is mainly an importer's market. From 1973 to 2017, the country was relying only on the regulations concerning the use of X-ray equipment in terms of the 1973 Act. The South African medical device sector is now in a transition phase and importantly, the end of the transition period will not mark a point when the regulatory environment for medical devices is complete, for managing such a large and vast field as medical devices will always be work in progress, but it will nevertheless introduce a considerably higher level of quality to the management of medical devices in SA than ever before.

When designing and reviewing policies, operational procedures and practices, regulators should consider how they might support or enable economic growth for compliant businesses and other regulated entities (Hodges, 2020). They should ensure that their officers have the necessary knowledge and skills to support those they regulate. Regulators must have a clear understanding of how regulation and the way it is enforced can impact on the business communities and individual businesses. Our analysis has shed light, with the help of pre-existing literature, on the way in which different types of regulatory approaches can affect firm level capabilities. In our case study for example, we found that a more prescriptive, rigid

regulatory change can hamper innovative activity by reducing the attractiveness of engaging in R&D, constraining modes of commercialization, and creating lock-in effects that force the economy into suboptimal standards.

#### *Understanding the co-evolution of the regulatory regime (state) and firm-based institutional capabilities*

The general, the extent and nature of state intervention in the economy is a live discourse in the literature (Wong, 2005). Firm capabilities and state regulation are inseparable, emerge and co-evolve, they represent the behaviors that follow from rules and norms (Schotter, 2008). Viewed from a sectoral systems of innovation perspective, it is clear that the state is almost always involved in the innovation process, if only by virtue of its effect on the institutional environment and/or support for R&D activities (Malerba and Mani, 2009). The regulatory regime must therefore understand that, the opportunity provided to private actors such as MNCs to participate in the regulatory process, share information and collaborate, contributes to the improvement of their knowledge. In turn, improved knowledge increases the innovative potential of actors while it builds their bargaining power and increases the possibilities private actors have to influence their institutional environment (Pietrobelli and Rabellotti, 2011).

#### *Planning Regulatory activities*

Regulators ought to carry out their “regulatory activities”<sup>3</sup> in a way that supports those they regulate to comply and grow. Regulators should avoid imposing unnecessary regulatory burdens through their regulatory activities and should assess whether similar social, environmental and economic outcomes could be achieved by less burdensome means (Hodges, 2016). Regulators should choose proportionate approaches to those they regulate, based on relevant factors including, for example, business size and capacity. De Maria et al. (2018) conducted a study aimed at comparing the certification route that manufactures must respect for marketing a medical device in some African Countries and in European Union. The study found that in developing countries, poor regulatory control results in the use of substandard devices, and often it becomes a constraint for those wanting to produce, sell, or even donate these devices. Similarly, (Saidi, 2016) explores the importance of medical device regulation in promoting access to high quality, safe and effective medical devices. The study emphasizes that medical device regulation in developing countries helps to prevent the importation and use of substandard devices thereby protecting the users from falling prey to unscrupulous market influences that put patients’ lives at risk.

#### *Compliance activities*

Regulators should publish a set of clear standards, including a compliance and enforcement policy. These standards should clearly set out what businesses and regulated bodies should be able to expect from regulators. Standards should cover areas including providing advice

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<sup>3</sup> The term ‘regulatory activities’ refers to the whole range of regulatory options and interventions available to regulators.

and other support for compliance, responding to stakeholder views, setting fees and charges and the professional competency of officers. Service standards, including compliance and enforcement policies, should be published and easily accessible, including on the regulator's website, and clearly "labelled" as to when they were last reviewed and the date of the next review. Inspections can be an effective approach to achieving compliance, but are likely to be most effective when they are justified and targeted on the basis of an assessment of risk. In order to ensure the effectiveness of their inspection programmes, regulators should focus their greatest inspection effort on regulated entities where risk assessment shows that both, a compliance breach or breaches would pose a serious risk to a regulatory outcome, and there is high likelihood of non-compliance by regulated entities (BERR, 2007). By facilitating compliance through a positive and proactive approach, regulators can achieve higher compliance rates and reduce the need for reactive enforcement actions. However, regulators should be able to target those who deliberately or persistently breach the law

### *Evaluation*

State regulation and firm innovation processes are evolutionary processes that interact overtime and their co-evolution is facilitated by knowledgeable actors who wish to influence their institutional environment. Regulators must, therefore, have an ability to evaluate their activities in relation to their regulatory objectives and their organisation's strategic priorities. Evaluating regulatory activities entails an inquiry, after regulation has been put in place, into how it has changed behaviour as well as, ultimately, its impacts on conditions in the world (Coglianese, 2012). Regulators should have an understanding of the value of feedback from those they regulate, and the beneficiaries of regulation in informing future activities.

### **Conclusions**

Regulatory authorities in developing economies not only face challenges regarding their own capabilities, but also have to grapple with heterogeneous levels of technological and innovation capabilities in firms. This paper draws from a firm-level analysis of internally created knowledge, externally sourced knowledge and firm heterogeneity among medical device manufacturers in South Africa to consider the corresponding evolution, development and deployment of regulatory capabilities in firms in their efforts to comply with the country's health and allied products regulatory authority requirements. Our departure point is that regulatory compliance is and should not be an onerous or after-thought activity for firms in this sector, but an integral part of their processes for improving performance and enhance competitiveness. Viewed this way, regulatory compliance would seek to develop and leverage industry knowledge and regulatory capabilities to inform decision making within the firm and the wider ecosystem. There is a case here, as illustrated by the empirical data we drew from, of integrating regulatory compliance and the requisite capabilities into a business-enhancing strategy for managing regulatory change and on-going compliance. The strategy will aim to maximise efficiencies and cost savings, mitigate risk of regulatory failure and will harness the best possible ways of ensuring that relevant officials in the firm are not only aware of existing and new regulatory requirements, but are also able to assess the effectiveness of current compliance frameworks and to benchmark the company's compliance arrangements against established and evolving industry best practice. Establishing and deploying policies and

procedures for decision making which satisfy regulatory requirements and evolving expectations is a key part of the capability mix that is required.

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